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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/601,005	03/01/1996	KJELL BACKSTROM	06275/034001	2853

26161 7590 09/04/2003

FISH & RICHARDSON PC
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BOSTON, MA 02110

EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/04/2003

37

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Applicati n N .

08/601,005

Applicant(s)

BACKSTROM ET AL.

Examiner

Frank I Choi

Art Unit

1616

--The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

THE REPLY FILED 15 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 15 August 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


E.S. MARK CLARDY
PATENT EXAMINER
GROUP 1200-1616

Continuation of 2. NOTE: The proposed amendment indicates that the medicament is in solid particle form. However, Applicant does not appear to cite where in the specification support is provided for the amendment "solid". As such, it appears that this amendment constitutes new matter. Further, said limitation was not presented earlier, as such, this raises a new issue which requires further consideration and/or search..

Continuation of 5. does NOT place the application in condition for allowance because: No terminal disclaimer has been filed, as such, the rejections of claims 46, 54-58, 61-77, 80, 82, 83 and 96-101 over claims 1, 10-41, 48-62, 74-105, 114-127 of US Patent 6,524,557 is maintained. Examiner has duly considered Applicant arguments but deems them unpersuasive. As such, the rejection of claims 46, 54-77, 80-177 is maintained for the reasons of record set forth in the prior Office Action and the further reasons below. Applicant cites to Appendix A and Appendix B, however, as indicated in the last Office Action no Appendix A is attached and there is no Appendix B attached to the response. Until such a time as Appendix A and Appendix B are provided to Examiner so that Examiner may review their contents for probative value as to the issue of obviousness, Applicant's arguments constitute merely the arguments of counsel which do not constitute evidence sufficient to overcome the rejection herein. Applicant concludes that one of skill in the art would appreciate the medicaments formulated in an aqueous solution and medicaments formulated in non-aqueous, organic medium would behave very differently, as they have very different chemical and physical properties. Applicant does not appear to have provided any evidence which supports this conclusion or indicated what significance this conclusion has to the issue of obviousness. In any case, the formulation of aerosols in aqueous or non-aqueous form is well within the skill of the one of ordinary skill in the art, including the use of surfactants (Sequeira et al., column 5, lines 18-68, Column 6, lines 1-8). Also, contrary to Applicant's arguments, the prior art provides motivation to use alkyl saccharides in that they are non-toxic compared to other surfactants and increase bioavailability of the intranasally and buccally administered medicament (Meezan et al., Column 1, lines 54-59, Column 2, lines 49-65). Finally, since the amendment was not entered, Applicant arguments with respect to said amendment do not overcome the rejection herein. Nevertheless, for the reasons of record and as indicated above, since it is well within the skill of the art to prepare aerosols in aqueous or non-aqueous form, the fact that Meezan et al. discloses examples which are aqueous form does not overcome the rejection herein as the broad disclosure of Meezan et al. in view of the other prior art supports the rejection herein.